

Applicant(s): P. Bonutti
Application No.: 10/007,360
Examiner: E. Robert

Remarks

Claims 1, 5-7, 16, 22, 28, 29, 46-51, 64, 65, 69, 74- 84, 86, 87, 101-108, 116, 117, 119-135, 138, and 139 are pending in the application and are presented for the Examiner's review and consideration. In this Response, claims 1, 5-7, 16, 22, 28, 29, 46, 64, 65, 69, 74, 82, 83, 86, 101-108, 116, 117, 119-133, and 138 have been amended, claims 8, 9, 11, 12, 26, 27, 62, 63, 66-68, 109, 110, 112, 113, and 118 have been cancelled, and claim 139 has been added. Applicant believes the claim amendments, cancellations, addition, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §103(a)-Neufeld.

Claims 1, 5-9, 11, 12, 16, 26, 27, 29, 46-51, 62-68, 74-78, 120-124, 126, 128-135, and 138 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 3,842,824 to Neufeld. ("Neufeld"). The Examiner asserts that Neufeld shows:

A method comprising the step of positioning a retainer member, e.g. pin 10, in a portion of a bone in the patient's body, and connecting the retainer member with tissue that is to be secured. The step of positioning the member includes utilizing the member to form an opening in the portion of the bone. The portion of the bone is a first bone and the tissue to be secured is a second bone. (See Figure 1). Neufeld discloses the claimed invention except for the member being made of bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to practice the method of Neufeld with a member being made of bone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

As an initial matter, Applicant notes that claims 8, 9, 11, 12, 26, 27, 62, 63, and 66-68 have been cancelled, rendering the rejection to these claims moot. These claim cancellations have been effected to expedite prosecution and are not an indication as to the validity of the rejection with respect to these claims.

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For the reasons set forth below, Applicant respectfully submits that claims 1, 5-7, 16, 46-51, 64, 65, 74-78, 120-126, 128-135, and 138 are not taught or suggested by Neufeld.

Neufeld discloses a surgical pin formed of rigid material for joining bone sections in an area of fracture. (Abstract and FIG. 1). The pin 10 is straight and is of substantially uniform diameter throughout its entire extent except for the extreme front end 11, which is pointed and provided with one or more cutting edges. (Col. 2, lns. 28-32). The intermediate portion 14 of the pin is provided with a series of longitudinally shaped weakened portions or notches 15-20. (Col. 2, lns. 41-43). Pin 10 may be formed of titanium or any other suitable material which has similar properties of strength, fracturability in response to bending forces. (Col. 3, lns 6-8).

FIG. 1 illustrates three pins 10a, 10b, and 10c inserted through the neck of the femur 20 to secure the head 28 of the femur in position following a fracture at 29. (Col. 3, lns. 15-17). After each pin is securely in place, a substantial portion of it projects outwardly from the bone and through the patient's muscle and skin. (Col. 3, lns. 35-37). The surgeon then simply slips tube 23 and tool 22 over the exposed end of the pin and urges the tube 23 towards the bone until the free end 25 of the tube is aligned with the first notch external to bone 27. (Col. 3, lns. 37-42). Bending movement of 15 degrees or less in a direction which tends to spread the selected notch is all that is need to break the pin. (Col. 3, lns. 44-46). Because of the angular staggering of the notches, breakage of the pin at some point other than at a selected notice is extremely unlikely. (Col 3, lns, 59-61).

As such, Neufeld discloses a pin for securing portions of a bone on opposite sides of a fracture in the bone. After the pin is inserted in the bone, traversing the fracture, the protruding end of the pin is broken off, along a predefined notch in the pin.

In contrast, amended independent claim 1 recites a method of securing a first bone against movement relative to a second bone in a patient's body. The method includes positioning a retainer member formed of bone through the first bone and into the second bone, preventing relative movement between the first and second bones. Thereafter, the retainer member is broken to release the first and second bones for movement relative to each other.

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Similarly, amended independent claim 46 recites a method of securing a first bone in a patient's body against movement relative to a second bone in the patient's body, wherein the first and second bones are different bones in the patient's body. The method includes the steps of moving a retainer member into the first and second bones, retaining the first and second bones against movement relative to each other with the retainer member. Thereafter, the retainer member is broken to release the first and second bones for movement relative to each other.

Applicant respectfully submits that while Neufeld discloses breaking the pin, it is the end portion of the pin extending from the bone which is broken. Additionally, the pin is not broken to allow relative movement between bone portions on opposite sides of a fracture, but only to remove excessive portions of the pin. Neufeld discloses that it is extremely unlikely to break the pin at any other place than the selected notch. In fact, allowing relative movement between portions of the bone is contrary to the teaching of Neufeld, namely, joining bone sections in an area of fracture.

Accordingly, Applicant submits that Neufeld does not expressly or impliedly suggest all of the elements of claims 1 and 46. In light of the foregoing, amended independent claims 1 and 46 are respectfully submitted to be patentable over Neufeld. As claims 5-7, and 16 depend from claim 1 and claims 47-51, 64, and 65 depend from claim 46, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Neufeld at least for the same reasons.

Amended independent claim 74 recites a method of immobilizing a joint between first and second bone in a patient's body. The method includes moving a retainer member formed of bone through a portion of the first bone and into the second bone, and holding the first and second bones against movement relative to each other, wherein the first and second bones are different bones in the patient's body.

Applicant respectfully submits that Neufeld discloses a surgical pin formed of rigid material for joining bone sections in an area of fracture. The bone sections are necessarily part of the same bone on opposite sides of the fracture.

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Additionally, the pin is disclosed as being formed of titanium or any other suitable material which has similar properties of strength, fracturability in response to bending forces. Contrary to the Examiner statement that it would have been obvious to one having ordinary skill in the art at the time the invention was made to practice the method of Neufeld with a member being made of bone, bone would not have similar properties of strength, fracturability in response to bending forces as titanium. As such, Applicant submits the Neufeld teaches against using bone to form the pin.

Accordingly, Applicant submits that Neufeld does not expressly or impliedly suggest all of the elements of claim 74. In light of the foregoing, amended independent claim 74 is respectfully submitted to be patentable over Neufeld. As claims 75-78 depend from claim 74, these dependent claims necessarily include all the elements of their respective base claim.

Accordingly, Applicant respectfully submits that the dependent claims are allowable over Neufeld at least for the same reasons.

Analogous to independent claim 74, amended independent claim 120 recites a method of securing a first bone against movement relative to a second bone in a patient's body. The method includes moving a retainer member formed of bone through the first bone and into the second bone under the influence of force applied against a trailing end portion of the retainer member, wherein the first and second bones are different bones in the patient's body. Moving the retainer member through the first bone and into the second bone includes initiating formation of an opening in the first bone by transmitting force from a leading end portion of the retainer member to the first bone and enlarging the opening by continuing to transmit force from the leading end portion of the retainer member to the first bone.

As was the case for independent claim 74, Neufeld does not teach or suggest all of the elements of claim 120. For example, Neufeld is limited to a metallic pin for fracture fixation of a single bone. Claim 120 further recites initiating formation of an opening in the second bone by transmitting force from the leading end portion of the retainer member to the second bone and enlarging the opening by continuing to transmit force from the leading end portion of the retainer member formed of bone to the second bone. As previously noted, Neufeld teaches only one

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bone, i.e., joining sections of the bone across a fracture.

In light of the foregoing, amended independent claim 120 is respectfully submitted to be patentable over Neufeld. As claims 121-124 depend from claim 120, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Neufeld at least for the same reasons.

Amended independent claim 129 recites a method of securing a first bone against movement relative to a second bone in a patient's body. The method includes initiating formation of an opening in the first bone by applying force against the first bone with an end of a retainer member formed of bone. At least a portion of the retainer member is moved into the opening and the retainer member is connected to the tissue to be secured, wherein the tissue to be secured is a second bone in the patient's body. The steps of moving at least a portion of the retainer member formed of bone in the first bone and connecting the retainer member with the tissue to be secured includes moving a portion of the retainer member through the first bone into the second bone to prevent relative movement between the first and second bones. Thereafter, the retainer member is broken to release the first and second bones for movement relative to each other.

As was the case for the other independent claims (for example claims 1 and 46), Neufeld does not teach or suggest all of the elements of claim 129. In light of the foregoing, amended independent claim 129 is respectfully submitted to be patentable over Neufeld. As claims 130-135 and 138 depend from claim 129, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Neufeld at least for the same reasons.

Withdrawn Claims

In the Office Action, claim 125 was indicated as being withdrawn from further consideration as being drawn to a non-elected species. Applicant respectfully requests reconsideration of the withdrawal of claim 125.

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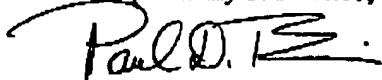
In the Response to the Restriction Requirement dated October 30, 2003 ("Restriction Response"), Applicant provided a listing of claims which read on the elected species. This listing inadvertently omitted claim 125. However, in the Restriction Response, Applicant provided a listing of the pending claims. This listing included claim 125. Applicant also provided a listing of withdrawn claims. Notably, this listing excluded claim 125. Furthermore, Applicant noted that claim 125 had been amended and that Applicant considered claim 125 to be generic to elected Species VI and non-elected Species VII and VIII. Accordingly, Applicant respectfully requests reconsideration of the withdrawal of claim 125. Applicant submits that this reconsideration is consistent with the examination of claims 126 and 128, which depend from claim 125.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-032-1).

Respectfully submitted,



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